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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. 10/735,582 12/11/2003 20784/4-CON Hans-Ulrich Demuth 4321 21710 04/19/2006 EXAMINER 7590 BROWN, RUDNICK, BERLACK & ISRAELS, LLP. CHISM, BILLY D BOX IP, 18TH FLOOR ART UNIT PAPER NUMBER ONE FINANCIAL CENTER BOSTON, MA 02111 1654

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)	
Office Action Summary				
		10/735,582	DEMUTH ET AL.	
	<b>,</b>	Examiner	Art Unit	
	The MAU INC DATE of this communication and	B. Dell Chism	1654	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).				
Status				
1)	Responsive to communication(s) filed on			
′=	•	—· action is non-final.		
3)	Since this application is in condition for allowa		osecution as to the merits is	
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims				
4)⊠ Claim(s) <u>13-24</u> is/are pending in the application.				
· · · · · · · · · · · · · · · · · · ·	4a) Of the above claim(s) is/are withdrawn from consideration.			
	5) Claim(s) is/are allowed.			
'=	⊠ Claim(s) <u>13-21</u> is/are rejected.			
	☑ Claim(s) <u>22-24</u> is/are objected to.			
	8) Claim(s) are subject to restriction and/or election requirement.			
Application Papers				
9) The specification is objected to by the Examiner.				
10)⊠ The drawing(s) filed on <u>11 December 2003</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).				
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).				
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.				
Priority under 35 U.S.C. § 119				
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:				
1. Certified copies of the priority documents have been received.				
	2. Certified copies of the priority documents have been received in Application No			
3. Copies of the certified copies of the priority documents have been received in this National Stage				
application from the International Bureau (PCT Rule 17.2(a)).				
* See the attached detailed Office action for a list of the certified copies not received.				
	•			
Attachment(s)				
	e of References Cited (PTO-892)	4) Interview Summary		
3) 🛛 Inform	e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) No(s)/Mail Date 12-11-03.	Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ate Patent Application (PTO-152)	

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### **DETAILED ACTION**

This is the first office action on the merits with claims 13-24 pending and under consideration. The Information Disclosure Statement filed 12-11-2003 was considered and is attached.

## Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 13-21 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 7and 13-14 of copending Application No. 09/745,776. Although the conflicting claims are not identical, they are not patentably distinct from each other because the class of compounds, i.e. prodrugs comprising stable DP IV inhibitors, encompasses those prodrug compounds of instant claims 13-21. It would be obvious to one of ordinary skill to utilize the instantly claimed species of that class disclosed in the 09/745,776 application.

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This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

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#### Claim Obections

3. Claims 22-24 are objected to for depending from rejected claims.

### Conclusion

4. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism, whose telephone number is (571) 272-0962. The examiner can normally be reached on M-F 08:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, PhD can be reached on (571) 272-0974.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**BDC** 

B. DELL CHISM PATENT EXAMINED